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510(k) SUMMARY

VivoMetric's Reusable Multiple-Patient LifeShirt

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

VivoMetrics, Inc.
121 North Fir Street, Suite E
Ventura, California 93001
Phone: 805-667-2225
Facsimile: 805-667-6846

Date Prepared: May 14, 2003

Name of Device and Name/Address of Sponsor

Reusable Multiple-Patient LifeShirt with VivoLogic Analysis Software

VivoMetrics, Inc.
121 North Fir Street, Suite E
Ventura, California 93001

Common or Usual Name

Programmable Diagnostic Computer

Classification Name

Programmable Diagnostic Computer

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Predicate Devices

LifeShirt with VivoLogic Analysis Software ("Reusable Single-Patient LifeShirt")

Purpose of 510(k)

The purpose of this Special 510(k) is to modify the LifeShirt. The only difference between the devices is that the new device is for reuse after washing by multiple adult patients while the device is currently marketed for reuse after washing by a single adult patient.

Intended Use

The Reusable Multiple-Patient LifeShirt is intended for use during daily activities of living and sleep, for the purpose of recording physiological data for later analysis by a physician. Respiration, ECG, pulse oximetry, blood pressure, and body position data may be collected. The system is intended to provide analysis of breathing patterns as an aid in classifying apneas as well as displaying heart rate changes from electrocardiographic waveforms in the wake and sleeping states as well as activities of daily living. The Reusable Multiple-Patient LifeShirt is indicated for reuse by multiple adult patients in applications that may include pharmaceutical studies in which respiratory information is a useful indicator, or the general healthcare market where patients may be monitored at home and the data provided to their physicians as an aid to diagnosis and treatment.

Technological Characteristics

The Reusable Multiple-Patient LifeShirt consists of the following components:

1. LifeShirt data acquisition system including the vest with inductive plethysmograph sensors, ECG sensors, a data cable and a connected Handspring Visor® device with software for data collection and storage onto a flash memory card;

2. LifeShirt data transfer software to transmit the data from the user's personal computer to the VivoMetrics Data Center;

3. VivoMetrics Data Center, a database operated by VivoMetrics personnel which stores and provides an audit trail for collected data; and

4. VivoLogic data analysis software for viewing and analyzing patient data.

Performance Data

Cleaning validation and functional validation was performed and demonstrate that the Reusable Multiple-Patient LifeShirt can be cleaned for multiple adult patient use and performs as intended following multiple washings.

Substantial Equivalence

The Reusable Multiple-Patient LifeShirt has the same intended use, principles of operation, and technological characteristics as the predicate device. The only difference between the Reusable Multiple-Patient LifeShirt and the Reusable Single-Patient LifeShirt is that the Reusable Multiple-Patient LifeShirt may be reused after washing by multiple adult patients and the Reusable Single-Patient LifeShirt may be reused after washing by a single adult patient. The difference in the number of users of the Reusable Multiple-Patient LifeShirt does not affect the device's diagnostic effect, which is to monitor the same physiological parameters as the predicate device, i.e., respiration, ECG, pulse oximetry, blood pressure, and body position, during activities of daily life and sleep for analysis by a physician. VivoMetrics has validated the ability of the cleaning process recommended in the Reusable Multiple-Patient LifeShirt User Guide to clean the device, as well as validated the functionality of the device after multiple washings. Thus, the Reusable Multiple-Patient LifeShirt is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2003

Hogan & Hartson LLP
c/o Mr. Howard M. Holstein
Regulatory Counsel
555 Thirteenth Street NW
Washington, DC 20004

Re: K031550
Trade Name: Reusable Multiple-Patient LifeShirt with VivoLogic Analysis Software
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: May 16, 2003
Received: May 16, 2003

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

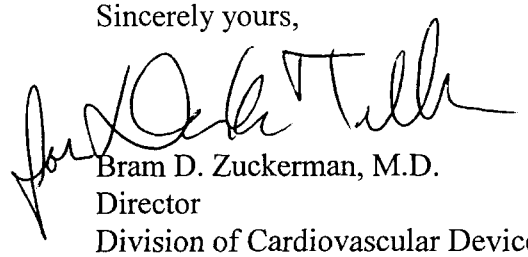
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K031550

Device Name: Reusable Multiple-Patient LifeShirt with VivoLogic Analysis Software

Indications for Use:

The Reusable Multiple-Patient LifeShirt is intended for use during daily activities of living and sleep, for the purpose of recording physiological data for later analysis by a physician. Respiration, ECG, pulse oximetry, blood pressure, and body position data may be collected. The system is intended to provide analysis of breathing patterns as an aid in classifying apneas as well as displaying heart rate changes from electrocardiographic waveforms in the wake and sleeping states as well as activities of daily living. The Reusable Multiple-Patient LifeShirt is indicated for reuse by multiple adult patients in applications that may include pharmaceutical studies in which respiratory information is a useful indicator, or the general healthcare market where patients may be monitored at home and the data provided to their physicians as an aid to diagnosis and treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031550